

PTO-SB 080 (04-03)

Approved for use through 04/30/2003, OMB 0651-0031

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Page

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of

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**Complete if Known**

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Nichols, Christopher J.
Attorney Docket Number	020167-000120US

**U.S. PATENT DOCUMENTS**

Examiner	Cite No.	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
CSN	AA	US-5,422,110		06/06/1995	Potter et al.	
CSN	AB	US-SN 10/054,873		06/06/1995	Gan	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
CSN	AC	EP	0 645 454	A2	03/23/1995	Lunin et al.		
CSN	AD	WO	96/23868	A1	08/08/1996	G.D. Searle & Co		
CSN	AE	CA	1,341,211		03/27/2001	Hoechst Aktiengesellschaft		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CSN	AF	BIOCHIM. DATABASE, Accession number: P00407207026. Samuelsson et al., 1994, "Enhanced in vitro refolding of insulin-like growth factor I using a solubilizing fusion partner," <i>Biochemistry</i> 33(14):4207-4211 (abstract)	
CSN	AG	BIOCHIM. DATABASE, Accession number: P00407207026. Klappa et al., 1997, "Interactions between protein disulphide isomerase and peptides," <i>European Journal of Biochemistry</i> 248(1):37-42 (abstract)	

Examiner Signature	<i>Gillian B</i>	Date Considered	9/11/2003
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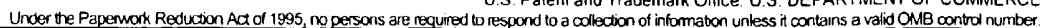
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Sheet	1	of	3
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Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	<del>Soud, Christine J.</del>
Attorney Docket Number	020167-000120US

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G. Nichols

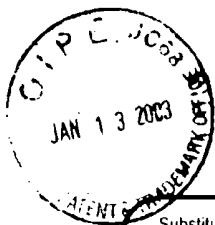
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**INFORMATION DISCLOSURE  
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Sheet

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of

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**Complete if Known**

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Saeed, Christine J.
Attorney Docket Number	020167-000120US

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**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SW	AG	U. Shinde and M. Inouye, "Intramolecular chaperones and protein folding," <i>TIBS</i> , (1993), Vol. 18, pp. 442-446.	
SW	AH	M. Inouye, "Intramolecular Chaperone: The Role of the Pro-Peptide in Protein Folding," <i>Enzyme</i> , (1991), Vol. 45, pp. 314-321.	
SW	AI	M. Ikenara, et al., "Synthesis of a gene for human growth hormone and its expression in <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , (Oct. 1984), Vol. 81, pp. 5956-5960.	
SW	AJ	Watson et al., <i>Recombinant DNA—A Short Course</i> , Scientific American Books, W.H. Freeman Co., NY, (1983), pp. 231-241.	
SW	AK	Norman and Litwack, "Pancreatic Hormones: Insulin and Glucagon," in <i>Hormones</i> , Academic Press, Inc., NY, (1987), pp 264-317.	
SW	AL	I. Johnson, "Human Insulin from Recombinant DNA Technology," <i>Science</i> , (Feb. 11, 1983), Vol. 219, pp. 632-637.	
SW	AM	D. Williams, et al., "Cytoplasmic Inclusion Bodies in <i>Escherichia coli</i> Producing Biosynthetic Human Insulin Proteins," <i>Science</i> , (Feb. 5, 1982), Vol. 215, pp. 687-689.	
SW	AN	R. Burgess, "Protein Purification," in <i>Protein Engineering</i> , Oxender, D.L., Fox, C.F., Eds., Alan R. Liss, Inc, NY, (1987), pp. 71-82.	
SW	AO	R.E. Chance, et al., "The Production of Human Insulin Using Recombinant DNA Technology and a New Chain Combination Procedure," in <i>Peptides: Synthesis-Structure-Function</i> , Pierce Chem. Co., Rockford, IL, (1981), pp. 721-728.	
SW	AP	B.H. Frank and R.E. Chance, "The Preparation and characterization of human insulin of recombinant DNA origin," in <i>Therapeutic Agents Produced by Genetic Engineering "Quo Vadis?" Symposium</i> , (May 29-30, 1985), Sanoff Group, Toulouse-Labège, France, pp. 137-148.	
SW	AQ	R.E. Chance, et al., "Chemical, Physical, and Biological Properties of Recombinant Human Insulin," in J. L. Gueriguian <i>Insulins, Growth Hormone, and Recombinant DNA Technology</i> , Raven Press, NY, (1981), pp. 71-85.	
SW	AR	R. D. Johnson, "The Processing of Biomacromolecules: A Challenge for the Eighties," <i>Fluid Phase Equilib.</i> , (1986), 29:109-123.	
SW	AS	D. V. Goeddel, et al., "Expression in <i>Escherichia coli</i> of chemically synthesized genes for human insulin," <i>Proc. Natl. Acad. Sci. USA</i> , (Jan. 1979), No. 1, pp. 106-110.	

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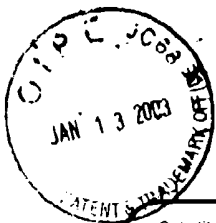
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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 3 of 3**Complete if Known**

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Saeed, Christine J.
Attorney Docket Number	020167-000120US

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**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AT	J. P. Burnett, "Commercial Production of Recombinant DNA-Derived Products," in <i>Experimental Manipulation of Gene Expression</i> , Academic Press, NY, (1983), pp. 259-277.	
	AU	J. Etienne-Decent, "Regulation of Protein Synthesis," in <i>Genetic Biochemistry: From Gene to Protein</i> , Ellis Horwood Limited, Chichester, U.K., (1988), pp. 125-127.	
	AV	S. M. Wheelwright, <i>Protein Purification: Design and Scale up of Downstream Processing</i> , Oxford University Press, NY, (1991), p.217.	
	AW	B.H. Frank and R.E. Chance, "Two Routes for Producing Human Insulin Utilizing Recombinant DNA Technology," <i>Munch. Med. Wschr.</i> , (1983), Vol. 125, Suppl. 1, pp. S14-S20.	
	AX	E. P. Kroeft, et al, "Production Scale Purification of Biosynthetic Human Insulin by Reversed-Phase High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , (1989), Vol. 461, pp. 45-61.	
	AY	H. V. Tottrup and S. Carlsen, "A Process for the Production of Human Proinsulin in <i>Saccharomyces cerevisiae</i> ," <i>Biotechnol. Bioeng.</i> , (1990), Vol. 35, pp. 339-348.	
	AZ	L. R. Castellanos-Serra, et al., "Expression and folding of an interleukin-2-proinsulin fusion protein and its conversion into insulin by a single step enzymatic removal of the C-peptide and the N-terminal fused sequence," <i>FEBS Letters</i> , (1996), Vol. 378, pp. 171-176.	
	BA	L. Villa-Komaroff, et al., "A bacterial clone synthesizing proinsulin," <i>Proc. Natl. Acad. Sci. USA</i> , (Aug. 1978), Vol. 75, No. 8, pp. 3727-3731.	
	BB	L. Thim, et al., "Secretion and processing of insulin precursors in yeast," <i>Proc. Natl. Acad. Sci. USA</i> , (Sept. 1986), Vol. 83, pp. 6766-6770.	
	BC	I. V. Diers et al., "Yeast Fermentation Processes for Insulin Production," in Y. H. Chiu <i>Drug Biotechnology Regulations: Scientific Basis and Practices</i> , Marcel Dekker, Inc., NY, (1991), pp. 166-176.	
	BD	M. R. Ladisch and K. L. Kohlmann, "Recombinant Human Insulin," <i>Biotechnol. Prog.</i> , (1992), Vol. 8, pp. 469-478.	

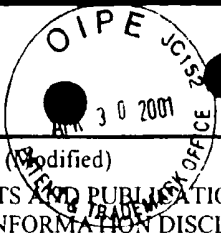
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FORM PTO-1449 (Modified)		Attorney Docket No.: 20167-000120US		Application No.: 09/423,100		
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Dr. Zhong-Ru Gan		Group: <del>1798</del> 1647		
		Filing Date: October 29, 1999				
Reference Designation		U.S. PATENT DOCUMENTS			Page 1	
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
<u>EN</u> AA	6,001,604	12/14/99	Hartman et al.			
<u>EN</u> AB	4,916,212	04/10/90	Markussen et al.			
<u>EN</u> AC	4,342,832	08/03/82	Goeddel et al.			
<u>EN</u> AD	5,254,463	10/19/93	de Boer et al.			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
<u>EN</u> AE	WO 96/20724	07/11/96	PCT			
<u>EN</u> AF	WO 97/18233	05/22/97	PCT			
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
EXAMINER		<u>G. M. L. S.</u>		DATE CONSIDERED		<u>3/6/2003</u>

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